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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,176	01/12/2004	Mark B. Knudson	14283.1USI7	2095

7590 04/24/2006

Merchant & Gould P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903

EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,176	KNUDSON ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a method, classified in class 607, subclass 3.

II. Claims 11-17, drawn to an apparatus, classified in class 607, subclass 40.

III. Claim 18, drawn to a neurostimulator, classified in class 607, subclass 60.

IV. Claims 19-21 and 23, drawn to methods, classified in class 607, subclass 2.

V. Claim 22, drawn to an apparatus, classified in class 607, subclass 60.

VI. Claim 24, drawn to a method, classified in 607, subclass 2.

VII. Claims 25-31, drawn to methods, classified in class 607, subclass 46.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another and materially different apparatus such as one that does not include a neurostimulator for generating an electrical output signal or a blocking signal generator, but rather the process may be practiced by an apparatus with no electrical stimulation or electrical blocking capabilities comprising an implantable medical device which releases a neural conduction stimulation at one site via a drug delivery device and which applies neural a conduction block at a different site that is comprises a pharmacologic or cryogenic block.

3. Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another and materially different apparatus such as one that does not include a neurostimulator for generating an electrical output signal or a blocking signal generator for generating a blocking signal, but rather the process may be practiced by an apparatus with no electrical stimulation or electrical blocking capabilities comprising an implantable medical device which releases a neural conduction stimulation at one site via a drug delivery device and which applies a neural conduction block at a different site that is a pharmacologic or cryogenic block. In addition the process as claimed can be practiced by another and materially different apparatus such as one that does not have programming means for selectively programming the parameters of an electrical signal generated by an implantable electrical signal generator, but rather the process may be practiced by an apparatus which has pre-programmed electrical stimulation and blocking parameters that can not be changed or selected.

4. Inventions I and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require detecting the occurrence of a predetermined

event associated with the eating disorder of interest and upon detection of the predetermined event, activating the device to apply both a stimulation signal and a blocking signal to the nerve. The subcombination has separate utility such as use by itself or with a method that involves external activation via telemetry.

5. Inventions I and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another and materially different apparatus such as one that does not include a neurostimulator for generating an electrical output signal or a blocking signal generator, but rather the process may be practiced by an apparatus with no electrical stimulation or electrical blocking capabilities comprising an implantable medical device which releases a neural conduction stimulation at one site via a drug delivery device and which applies a neural conduction block at a different site that is a pharmacologic or cryogenic block. In addition, the process as claimed can be practiced by another and materially different apparatus such as one that does not include an implantable lead assembly, but rather the process may be practiced by an apparatus that wirelessly transmits stimulation and/or blocking signals from an external pulse generator to an implanted telemetry receiving electrode/drug delivery device.

6. Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together, the have different designs, modes of operation and effects.

Specifically, the invention defined by Group I does not include controlling the function of a neurostimulator by selecting parameters of an electrical output signal, but rather the invention of Group I may be practiced by an apparatus with no electrical stimulation or electrical blocking capabilities comprising an implantable medical device which releases a neural conduction stimulation at one site via a drug delivery device and which applies a neural conduction block at a different site that is a pharmacologic or cryogenic block.

7. Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together, the have different designs, modes of operation and effects. Specifically, the invention defined by Group I does not include bilateral stimulation of a patient's right and left vagus nerve. Group I may be practiced by an apparatus with no electrical stimulation or electrical blocking capabilities comprising an implantable medical device which releases a neural conduction stimulation at one nerve site via a drug delivery device and which applies a neural conduction block at a different site that is a pharmacologic or cryogenic block.

8. Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not include programming means for selectively programming the parameters of the electrical signal generated by the generator. The

subcombination has separate utility such as use by itself or use with an apparatus that does not have programming means for selectively programming the parameters of an electrical signal generated by an implantable electrical signal generator, but rather the subcombination may be an apparatus which has pre-programmed electrical stimulation and blocking parameters that can not be changed or selected.

9. Inventions IV and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. Specifically, the apparatus may be used with a process which does not include detecting the occurrence of a predetermined event associated with an eating disorder of interest and upon detection of the predetermined event activating the neurostimulator device, but rather the apparatus may be used with a process that uses a patient/physician/user activation device, external to the implanted device, that telemetrically sends an activation signal to the neurostimulator.

10. Inventions II and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a sensor means electrically coupled to the

neurostimulator for detecting an occurrence of a predetermined event associated with an eating disorder of interest. The subcombination has separate utility such as use by itself or use with a patient/physician/user activation device, external to the implanted device, which telemetrically sends an activation signal to the neurostimulator.

11. Inventions VI and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as a process which does not include selecting parameters of an electrical output signal of a pulse generator, but rather the apparatus may include stimulating/blocking where the stimulation is pre-programmed with parameters that can not be changed or selected.

12. Inventions VII and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as a process which does not include bilateral stimulation of both the right and left vagi, but rather with a process that only stimulates one branch of the vagus nerve (i.e. only the right side or only the left side).

13. Inventions IV and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another

and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practice by another and materially different apparatus such as an apparatus that does not comprise programming means, but rather with an apparatus where the stimulation parameters are pre-programmed/pre-determined and cannot be changed/modified/selected.

14. Inventions III and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. See MPEP § 806.05(d). In the instant case, subcombination V has separate utility such as by itself or use in a method which does not require any programming of the stimulation parameters, such as use in a method where the apparatus comprises stimulation parameters that are pre-programmed/pre-determined and cannot be changed/modified/selected.

15. Inventions VI and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practice by another and materially different apparatus such as an apparatus that does not apply an electrical blocking signal, but rather with an apparatus that applies a pharmacological or cryogenic blocking signal.

16. Inventions VII and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be

used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as a process which does not include bilateral stimulation of both the right and left vagi, but rather with a process that only stimulates one branch of the vagus nerve (i.e. only the right side or only the left side).

17. Inventions IV and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practice by another and materially different apparatus such as an apparatus that does not apply an electrical blocking signal, but rather with an apparatus that applies a pharmacological or cryogenic blocking signal.

18. Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not discloses as capable of use together and they have different designs, modes of operation and effects. Specifically, the invention defined by Group IV does not include controlling the function of a neurostimulator by selecting parameters of an electrical output signal, but rather the invention of Group IV may be practiced by an apparatus with no electrical stimulation or electrical blocking capabilities comprising only an implantable drug delivery device which releases a neural conduction stimulation at one site via a drug delivery device and which applies a conduction block at a different site that is a pharmacologic or cryogenic block.

19. Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have different designs, modes of operation and effects. Specifically, the invention defined by Group IV does not include bilateral stimulation of a patient's right and left vagus nerve. Group IV may be practiced by an apparatus with no electrical stimulation or electrical blocking capabilities comprising only an implantable drug delivery device which releases a neural conduction stimulation at one nerve site via a drug delivery device and which applies a conduction block at a different site (on the same nerve branch) that is a pharmacologic or cryogenic block.

20. Inventions VI and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In the instant case, the apparatus as claimed can be used to practice another and materially different process such as use with a process that does not require any programming of the stimulation parameters, but rather with a process where the stimulation parameters are pre-programmed/pre-determined and cannot be changed/modified/selected.

21. Inventions VII and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In the instant case, the

apparatus as claimed can be used to practice another and materially different process such as use with a process that does not require bilateral stimulation, but rather use with a process that only includes stimulation/blocking on one branch of the vagi.

22. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclose as capable of use together and they have different designs, modes of operation, and effects. Specifically, the invention defined by Group VI does not include bilateral stimulation, but rather only includes stimulation/blocking on one branch of the vagi. Also, the invention defined by Group VII does not include selecting of parameters for the stimulation and may be practiced where the stimulation parameters are pre-programmed/pre-determined and cannot be changed/modified/selected.

23. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

24. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

25. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel
Examiner
Art Unit 3766

04/19/06

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766